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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats

The Patient Safety and Quality Improvement Act of 2005 (hereafter the Patient Safety Act), 42 U.S.C. 299b-21 to 299b-26, was enacted in response to growing concern about patient safety in the United States and the Institute of Medicine's 1999 report, *To Err is Human: Building a Safer Health System*. The goal of the statute is to improve patient safety by providing an incentive for health care providers to work voluntarily with experts in patient safety to reduce risks and hazards to the safety and quality of patient care. The Patient Safety Act signifies the Federal Government's commitment to fostering a culture of patient safety among health care providers; it offers a mechanism for creating an environment in which the causes of risks and hazards to patient safety can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. It provides for the voluntary formation of Patient Safety Organizations (PSOs) that can collect, aggregate, and analyze confidential information reported voluntarily by health care providers. By analyzing substantial amounts of patient safety event information across multiple institutions, PSOs will be able to identify patterns of failures and propose measures to eliminate or reduce patient safety risks and hazards.

In order to implement the Patient Safety Act, the Department of Health and Human Services (HHS) issued the Patient Safety and Quality Improvement Final Rule (hereafter the Patient Safety Rule), 42 CFR part 3, which became effective on January 19, 2009. The Patient Safety Rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events. In addition, the Patient Safety Rule outlines the requirements that entities must meet to become PSOs and the process by which the Secretary of HHS (hereafter the Secretary) will review and accept certifications and list PSOs.

In addition to the Patient Safety Act and the Patient Safety Rule, HHS issued Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (hereafter Guidance) on December 30, 2010. The Guidance addresses questions that have arisen regarding the legal obligations of PSOs when they or the organization of which they are a part report certain information to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. This includes providing the FDA with access to its records, including access during an inspection of its facilities. This Guidance applies to all entities that seek to be a PSO, or are one currently, either alone or as a component of another organization that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations ("FDA-regulated reporting entities"). It also covers PSOs that are organizationally related to such FDA-regulated reporting entities (e.g., parent organizations, subsidiaries, sibling organizations).

When PSOs meet the requirements of the Patient Safety Act, the information collected and the analyses and deliberations regarding the information receive Federal confidentiality and privilege protections under this legislation. The Secretary delegated authority to the Director of the Office for Civil Rights (OCR) to enforce the confidentiality protections of the Patient Safety Act. 71 Federal Register 28701-28702 (May 17, 2006). OCR is responsible for enforcing protections regarding patient safety work product (PSWP), which generally includes information that could improve patient safety, health care quality, or health care outcomes and (1) is assembled or developed by a provider for reporting to a PSO and is reported to a PSO or (2) is developed by a PSO for the conduct of patient safety activities. Civil money penalties may be imposed for knowing or reckless impermissible disclosures of PSWP. AHRQ implements and administers the rest of the Patient Safety Act's provisions.

Pursuant to 42 CFR 3.102, an entity that seeks to be listed as a PSO by the Secretary must certify that it meets certain requirements and, upon listing, will meet other criteria. To remain listed for renewable three-year periods, a PSO must recertify that it meets these obligations and will continue to meet them while listed. The Patient Safety Act and Patient Safety Rule also impose other obligations, discussed below, that a PSO must meet to remain listed. In order for the Secretary to administer the Patient Safety Act and Rule, the entities seeking to be listed and to remain listed must complete the proposed forms.

Method of Collection

With this submission, AHRQ is requesting approval of the following proposed administrative forms.

1. PSO Certification for Initial Listing Form. This form, which is to be completed by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period, contains certifications that the entity meets the requirements for listing as a PSO, in accordance with 42 U.S.C. 299b-24(a)(1) and 42 CFR 3.102.

2. PSO Certification for Continued Listing Form. In accordance with 42 U.S.C. 299b-24(a)(2) and the Patient Safety Rule, this form is to be completed by a listed PSO seeking continued listing as a PSO by the Secretary for an additional three year period.

3. PSO Two Bona Fide Contracts Requirement Certification Form. To remain listed, a PSO must have contracts with more than one provider, within successive 24 month periods, beginning with the date of its initial listing. 42 U.S.C. 299b-24(b)(1)(C). This form is to be used by a PSO to certify whether it has met this requirement.

4. PSO Disclosure Statement Form. A PSO must submit this form when it (i) has a Patient Safety Act contract with a health care provider and (ii) it has financial, reporting, and contractual relationships with that

contracting provider or is not independent of that contracting provider. 42 U.S.C. 299b-24(b)(1)(E); 42 CFR 3.102(d)(2).

5. PSO Profile Form. This form, previously called the PSO Information Form, gathers information on PSOs and the type of health care providers and settings that they are working with to conduct patient safety activities in order to improve patient safety. It is designed to collect a minimum level of data necessary to develop aggregate statistics relating to the Patient Safety Act, including types of institutions participating and their general location in the US. This information will be included in AHRQ's annual quality report, required by 42 U.S.C. 299b-23(c).

6. PSO Change of Listing Information Form. The Secretary is required under 42 U.S.C. 299b-24(d) and the Patient Safety Rule to maintain a publicly available list of PSOs that includes, among other information, contact information for each entity. The Patient Safety Rule, section 3.102(a)(vi), also requires that a PSO must promptly notify the Secretary during its period of listing if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes. This form is to be used by a PSO to revise its listing information, to include updating its contact information that will be used in the Secretary's list of PSOs.

The forms described above, other than the PSO Change of Listing Information Form, are revised collection instruments that were previously approved by OMB in 2008 and 2011. These forms, along with the new PSO Change of Listing Information Form, will be used by AHRQ to obtain information necessary to implement the Patient Safety Act and Patient Safety Rule, e.g., obtaining initial and subsequent certifications from entities seeking to be listed as PSOs and for making the statutorily-required determinations prior to and during an entity's period of listing as a PSO. This information is used by the PSO Program Office housed in AHRQ's Center for Quality Improvement and Patient Safety.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form. The purpose of this collection is to allow OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with the OCR so that there is a basis for initial processing of those complaints.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (hereafter Common Formats). Pursuant to 42 U.S.C. 299b-23(b), AHRQ coordinates the development of the Common Formats that allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events.

Estimated Annual Respondent Burden

While there are a number of information collection forms described below, the forms will be implemented at different times and frequency due to the voluntary nature of seeking listing and remaining listed as a PSO, filing a Patient Safety Confidentiality Complaint Form, and using the Common Formats. Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information, and Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to provide the requested information. The total burden hours are estimated to be 100,704 hours annually and the total cost burden is estimated to be \$3,618,294.72 annually.

PSO Certification for Initial Listing Form:

The average annual burden for the collection of information requested by the certification forms for initial listing is based upon a total average estimate of 17 respondents per year and an estimated time of 18 hours per response. The estimated response number not only includes submissions by entities that are successfully listed as PSOs, but also submissions by entities that submit an initial listing form that do not become a PSO. During the past three years, AHRQ has provided substantial technical assistance about the PSO Program, including to entities seeking initial listing. After submitting an initial listing form, an entity may withdraw its form or submit a revised form, particularly after receiving technical assistance from AHRQ. In addition, AHRQ, on behalf of the Secretary, may deny listing if an entity does not meet the requirements of the Patient Safety Act and Patient Safety Rule or if the entity does not provide other information determined to be necessary to make the listing determination, such as a lack of response to requests for clarifications by AHRQ on the attestations and responses on the form. This collection of information takes place on an ongoing basis.

Certification for Continued Listing Form:

The average annual burden for the collection of information requested by the certification form for continued listing is an estimated time of eight hours per response and 16 responses annually. The Certification for Continued Listing Form must be completed by any interested PSO at least 75 days before the end of its current three-year listing period. The number of respondents is based upon the estimate that 65% of the projected 77 listed PSOs will submit forms for continued listing. The estimated number of responses reflects the fact that a PSO can choose to voluntarily relinquish its status as a PSO for any reason or that a PSO can choose to not seek continued listing and allow its listing to expire. In addition, AHRQ, on behalf of the Secretary, can revoke the listing of a PSO if it is found to no longer meet the requirements of the Patient Safety Act or Patient Safety Rule. Therefore, AHRQ estimates that approximately two thirds of PSOs will seek continued listing and submit the form.

Two Bona Fide Contracts Requirement Certification:

The average annual burden for the collection of information requested by the two-contract requirement is based upon an estimate of 30 respondents per year and an estimated one hour per response. This collection of information takes place when the PSO notifies the Secretary that it has entered into two contracts.

Disclosure Statement Form:

AHRQ assumes that only a small percentage of entities will need to file a disclosure form. However, AHRQ is providing a high estimate of 2 respondents and thus presumably overestimating respondent burden. The average annual burden estimate of six hours for the collection of information requested by the disclosure form is based upon an estimated three hours per response. This information collection takes place when a PSO first reports having any of the specified types of additional relationships with a health care provider with which it has a contract to carry out patient safety activities.

Profile Form:

The overall annual burden estimate of 231 hours for the collection of information requested by the PSO Profile Form is based upon an estimate of 77 respondents per year and an estimated three hours per response. Newly listed PSOs first report in the calendar year after their listing by the Secretary.

Patient Safety Confidentiality Complaint Form:

The overall annual burden estimate of one hour for the collection of information requested by the form is based on an estimate of three respondents per year and an estimated 20 minutes per response. OCR's information collection using this form will not begin until after there is an allegation of a violation of the statutory protection of PSWP.

PSO Change of Listing Information Form:

The average annual burden for the collection of information requested by the change of listing information forms is based upon a total average estimate of 24 respondents per year and an estimated time of five minutes per response. This collection of information takes place when the PSO notifies the Secretary that its listing information has changed.

Common Formats:

AHRQ estimates that 5% FTE of a Patient Safety Manager at a hospital will be spent to administer the Common Formats, which is approximately 100 hours a year. In the previous submission, AHRQ estimated that 1,000 hospitals would be using the Common Formats in year 3. AHRQ estimates the number of hospitals using Common Formats will remain level for the next three years at 1,000 hospitals.

Exhibit 1. Estimated Annualized Burden Hours

Form	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden Hours
Certification for Initial Listing Form*	17	1	18	306
Certification for Continued Listing Form*	16	1	8	128
Two Bona Fide Contracts Requirement Form**	30	1	1	30
Disclosure Statement Form***	2	1	3	6
Profile Form****	77	1	3	231
Patient Safety Confidentiality Complaint Form***	3	1	20/60	1
Change of Listing Information***	24	1	05/60	2
Common Formats	1,000	1	100	100,000
Total***	1,169	NA	NA	100,704

*AHRQ expects the number of PSOs to remain relatively stable, with 65% of listed PSOs seeking continued listing. The number of new entities seeking listing as PSOs and PSOs seeking continued listing will be offset by the number of entities that will voluntarily relinquish their status as a PSO, allow their listing to expire, or have their listing revoked for cause by AHRQ.

**The Two Bona Fide Contracts Requirement Form will be completed by each PSO within the 24-month period after listing by the Secretary.

***The Disclosure Statement Form and the Change of Listing Information form may be submitted by individual PSOs in different years. Due to changes in their operations, a PSO can submit more than one Change of

Listing Information in a year. OCR is anticipating considerable variation in the number of complaints per year. Hence, the total for each year is expressed as an average of the expected total over the three year collection period.

**** The Profile Form collects data from listed PSOs each calendar year. The prior version of this form, the PSO Information Form, began collecting data from listed PSOs each calendar year in 2011.

Exhibit 2. Estimated annualized cost burden

Form	Number of Respondents	Total burden hours	Average hourly wage rate*	Total cost
Certification for Initial Listing Form	17	306	\$35.93	\$10,994.58
Certification for Continued Listing Form	16	128	\$35.93	\$4,599.04
Two Bona Fide Contracts Requirement Form	30	30	\$35.93	\$1,077.90
Disclosure Statement Form	2	6	\$35.93	\$215.58
Profile Form	77	231	\$35.93	\$8,299.83
Patient Safety Confidentiality Complaint Form	3	1	\$35.93	\$35.93
Change of Listing Information	24	2	\$35.93	\$71.86
Common Formats	1,000	100,000	\$35.93	\$3,593,000.00
Total	1,169	100,704	NA	\$3,618,294.72

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupations, 29-0000, National Compensation Survey, May 2013, "U.S. Department of Labor, Bureau of Labor Statistics." (http://www.bls.gov/oes/current/oes_nat.htm#29-0000).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care

information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ' s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 1, 2014

Richard Kronick,
AHRQ Director.

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